Section 6 **510(k) Summary** **FEB 0 4 2013**

510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Cianna Medical 6 Journey # 125 Aliso Viejo, CA 92656
DATE PREPARED:	2-3-2013
CONTACT PERSON:	Gary Mocnik Cianna Medical 6 Journey Aliso Viejo, CA 92656 Phone: (949)360.0059 x134 Fax: (949) 297.4527 Email: gmocnik@ciannamedical.com
TRADE NAME:	Cianna Medical Tissue Marker and Delivery System
COMMON NAME:	Temporary Tissue Marker
CLASSIFICATION NAME:	Implantable Clip, 21 CFR 878.4300
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	PBY
PREDICATE DEVICES:	Mixed Media Marker- K102506 TuMark Flex Tissue Marking System- K111692 Hydromark (K090501)

Substantially Equivalent To:

The Cianna Medial Tissue Marker and Delivery System is substantially equivalent in intended use, principal of operation and technological characteristics to the Mixed Media Marker (K102506), TuMark Flex Tissue Marking System (K111692), and the Hydromark (K090501). The Cianna Medical Tissue Marker differs from the predicates only in its intended implant duration. The predicates are intended to be long term implants while the Cianna Medical Tissue Marker is intended for implant duration of less than 30 days and is removed with the target tissue.

Description of the Device Subject to Premarket Notification:

The Cianna Medical Tissue Marker and Delivery System is comprised of an implantable marker and a delivery system.

The marker is comprised of a series of 1 mm diameter titanium "beads" which are constrained onto a heat shaped nitinol wire. The marker is preloaded within the lumen of the delivery system. Once percutaneously deployed from the delivery system, the marker maintains a coiled shape (approximately 4.5mm diameter by 5mm length) in the tissue. The marker is echogenic under Ultrasound, radiopaque under radiograph imaging.. The Cianna Medical Tissue Marker and Delivery System is provided sterile, and is for single use only.

Indication for Use:

The Cianna Medical Tissue Marker is intended to be placed percutaneously in the breast to temporarily (< 30 days) mark a lumpectomy site intended for surgical removal. Using ultrasound or radiography imaging guidance, the Cianna Tissue Marker is located and surgically removed with the target tissue.

Discuss of Technological Characteristics:

The Cianna Medical Tissue Marker and Delivery System has the same technological characteristics and is similar in overall design, materials and configuration compared to the predicates. The Cianna Medical Tissue Marker and Delivery System and the identified predicates are all radiographically visible marker elements positioned into tissue for visualization of the tissue site. The technical designs of the Cianna Medical Tissue Marker and the predicate devices are very similar, being composed of an array of biocompatible, radiopaque metals which are delivered into tissue via a needle delivery system.

Non-Clinical Performance Data

Performance testing was conducted to evaluate and characterize the performance of the Cianna Medical Tissue Marker System. Preclinical testing conducted included dimensional conformance evaluation, visual inspections, and design verification to confirm imaging equivalency, MRI compatibility testing, and biocompatibility testing based on the applicable elements of ISO 10993-1 shown below.

Test Performed	Standard	Test Result/Conclusion
ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells	ISO 10993-5	Passed. Non-cytotoxic
ISO Intracutaneous Reactivity Test	ISO 10993-10	Passed. The test requirements were met
Sensitization: Guinea Pig Maximization	ISO 10993-10	Passed Negative for evidence of sensitization
ISO Acute Systemic Injection Test	ISO 10993-11	Passed The test requirements were met
Material Mediated Rabbit Pyrogen Test	ISO 10993-10	Passed Non-Pyrogenic
Bacterial Mutagenicity Test-Ames Assay	ISO 10993-3	Passed Non-Mutagenic
In Vitro Mouse Lymphoma Assay	ISO 10993-3	Passed Non-Mutagenic (non-genotoxic and non-clastogenic)
In Vivo Mouse Micronucleus Assay	ISO10993-3	Passed Non-Mutagenic
30 Day Rabbit Implantation with Subchronic Toxicity	ISO 10993-6 ISO10993-11	Passed No local or systemic signs of toxicity

Clinical Data

This submission does not rely on clinical data to determine substantial equivalency to the predicate devices.

Basis for Determination of Substantial Equivalence:

Product	Intended Use	Principle of Operation	Overall Technological Characteristics
Cianna Medical Tissue Marker and Delivery System	The Cianna Medical Tissue Marker is intended to be placed percutaneously in the breast to temporarily (< 30 days) mark a lumpectomy site intended for surgical removal. Using ultrasound or radiography imaging guidance, the Cianna Tissue Marker is located and surgically removed with the target tissue.	Marker is implanted into tissue site for visualization of tissue site	Radiographically visible marker element(s)
Mixed Media Marker K102506	The Mixed Media Markers (MMM) are intended to be implanted into the body in situations where the location of specific anatomy, normal or diseased, needs to be marked for a future medical procedure. The MMM can be visualized using medical imaging devices; the MMM provides a reference from which treatment can be guided. MMM's not intended for use with ultrasonography.	SAME	SAME
TuMark Flex Tissue marking System K111692	The TuMark Flex is intended for radiographically and radiologically percutaneous marking of soft tissue, especially breast tissue, via a clip marker. The TuMark Flex is not indicated to be used with magnetic resonance imaging (MRI) techniques.	SAME	SAME
HydroMark Biopsy Site Marker K090501	The Biopsy Science LLC, HydroMark Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks and be permanently visible by x-ray and MRI	SAME	SAME

Conclusions Drawn:

As shown, the Cianna Medical Tissue Marker has the following similarities to the predicate devices:

- Similar intended use
- Similar design characteristics
- Same operating principal
- Same mechanism of action
- Similar technological characteristics

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Cianna Medical Tissue Marker System is determined by Cianna Medical, to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Cianna Medical
% Mr. Gary Mocnik
Vice President, Regulatory Affairs and Quality Systems
6 Journey, Suite 125
Aliso Viejo, California 92656

February 4, 2013

Re: K120804
Trade/Device Name: Cianna Medical Tissue Marker System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: PBY
Dated: January 18, 2013
Received: January 30, 2013

Dear Mr. Mocnik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K120804

Device Name: **Cianna Medical Tissue Marker System**

Indications for Use:

The Cianna Medical Tissue Marker is intended to be placed percutaneously in the breast to temporarily (< 30 days) mark a lumpectomy site intended for surgical removal. Using ultrasound or radiography imaging guidance, the Cianna Tissue Marker is located and surgically removed with the target tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use __X__
(Per 21 CFR 801 Subpart D)

Over-The-Counter Use_____
(Per 21 CFR 801 Subpart C)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K120804